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(71) Applicant: ESCALON MEDICAL CORP. [US/US]; 182 Tamarack Circle, Skillman, NJ 08558 (US).

(72) Inventors: JUHASZ, Tibor, 22 Newton Court, Irvine, CA 92715-4038 (US). BILLE, Josef, F.; Hermann-Löns-Weg 44/1, D-69118 Heidelberg (DE).

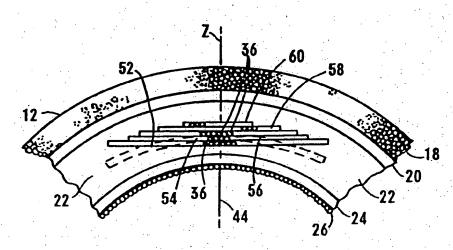
(74) Agents: NYDEGGER, Neil, K. et al.; Nydegger & Associates, Suite 950, 4350 La Jolla Village Drive, San Diego, CA 92122 (US).

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(54) Title: INTRASTROMAL PHOTO-REFRACTIVE KERATECTOMY

(57) Abstract

A method for performing intrastromal photo-refractive keratectomy in the comea (12) of an eye using a pulsed laser beam, includes the initial step of focusing the beam to a focal spot at a selected starting point in the stroma (22). The starting point is located at a predetermined distance behind the epithelium (18) of the comea. While focused on the starting point, the laser beam is pulsed to disrupt a volume of stromal tissue (36) which is substantially equal to the volume of the focal spot. Subsequently, the beam is focused in a patterned sequence to focal spots at other discrete points in the stroma. At each point the stromal tissue is photo-disrupted. With



this progressive pattern of photo-disruption, each spot is placed substantially adjacent a volume of previously disrupted tissue. The resultant photo-disrupted tissue creates a layer which is substantially centro-symmetrical around the optical axis. A plurality of layers can be removed to create a cavity in the stroma. When the cavity collapses, the corneal curvature is changed as desired.

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INTRASTROMAL PHOTOREFRACTIVE KERATECTOMY RELATED APPLICATION

This application is a continuation-in-part of copending U.S Patent Application Serial No. 08/151,726, filed 11/12/93, for Intrastromal Photorefractive Keratectomy.

FIELD OF THE INVENTION

The present invention pertains to methods for using lasers to accomplish ophthalmic surgery. More particularly, the present invention pertains to methods for reshaping the cornea of the eye to improve a patient's vision. The present invention is particularly, but not exclusively, useful as a method for intrastromal photorefractive keratectomy (ISPRK).

BACKGROUND OF THE INVENTION

It is known that the cornea of an eye can, in certain 15 instances, be surgically reshaped to correct and improve vision. Where the condition being corrected is myopia, or near-sightedness, the cornea is relatively flattened, whereas if hyperopia is being corrected, the cornea is relatively steepened. In either case, as more fully set forth below, there several different are types of ophthalmic surgical procedures which can be employed for this purpose. Although the types of procedures may vary, the ultimate object in correcting myopia, for example, is 25 Namely, the object is to cause the anterior surface of the cornea to be flattened, usually by reducing the center thickness so that it properly refracts light entering the eye for subsequent focussing on the retina of the eye.

The most common surgical operation for reshaping the cornea is a procedure known as radial keratotomy. This

procedure, which is used primarily to correct myopia, is performed by making a series of radial incisions on the surface of the cornea. These incisions extend from the outer edge of the cornea toward its center in spoke-like fashion to weaken selected sections of the cornea. With these weakened sections, the fluid pressure of the aqueous humor inside the eye will cause the cornea to deform. When intended for the myopic correction procedure, the desired deformation is a flattening of the cornea to provide proper light refraction for improved vision.

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In recent years, the use of cutting tools to make incisions into the cornea for vision corrections is gradually being replaced or supplemented by the use of new surgical procedures using lasers. Rather than making incisions, laser energy which reshape the cornea do so by actually removing corneal tissue. This is accomplished by a process which is generally known as photoablation. Heretofore, the photoablation of corneal tissue has been accomplished primarily by focussing laser energy onto the exposed anterior surface of the eye. The result which can be achieved is dependent on two interrelated factors. First, the particular laser system which is employed to generate a laser beam will significantly affect how the photoablation process can be accomplished. method by which the laser energy is manipulated to accomplish photoablation will effectively determine the efficacy of the procedure.

For ophthalmic laser systems, several different types of laser beams have been suggested. For example, U.S. Patent No. 4,665,913 which issued to L'Esperance, Jr. for an invention entitled "Method for Ophthalmological Surgery" discloses a corneal reshaping procedure using an excimer laser. As another example, U.S. Patent No. 4,907,586 which issued to Bille et al. for an invention entitled "Method for Reshaping the Eye", and which is assigned to the same

assignee as the present invention, discloses a corneal reshaping procedure which uses a pulsed laser beam.

Although using lasers for the removal of corneal tissue from the anterior surface of the cornea is known to be effective, the removal of tissue from the anterior surface requires photoablation of several layers of different types of tissues in the cornea. These include portions of the epithelium, Bowman's membrane and the The present invention recognizes that it is preferable to leave the epithelium and Bowman's membrane intact, and to limit the tissue removal to only the stroma. Removal of tissue from the stroma results in the creation of a specially shaped cavity in the stroma layer of the When the cornea deforms in the intended manner, the desired flattening of the cornea results. Further, the invention recognizes that internal tissue present photoablation, or more precisely "photodisruption", can be effectively accomplished using a pulsed laser energy if the irradiance of the beam, its focal spot size, and the proper layering of photo disruption sites are effectively controlled.

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It is an object of the present invention to provide a method for performing intrastromal photodisruption on the cornea of an eye using a pulsed laser beam which controls the irradiance of the laser beam to limit the amount of tissue which is subject to photodisruption. Another object of the present invention is to provide a method for intrastromal photorefractive keratectomy which controls the spot size and spot configuration of the laser beam to permit removal of stromal tissue by contiguous photodisruption at successively adjacent spots. another object of the present invention is to provide a method for intrastromal photodisruption which removes stromal tissue in a predetermined pattern of properly sized and shaped layers to attain the desired flattening of the cornea. Yet another object of the present invention is to

provide a method for intrastromal photodisruption which is relatively easy to perform and which is comparatively cost effective.

SUMMARY OF THE INVENTION

In accordance with the present invention, a method for 5 performing photodisruption and removal of tissue limited to the stroma in the cornea of an eye uses a pulsed laser beam which is sequentially focused to individual spots at a plurality of points in the stroma. Each focus spot has a 10 volume, rather than being a single Photodisruption of stromal tissue occurs at each spot where the beam is focused, and the volume of stromal tissue disrupted at each spot is approximately equal to the volume of the spot. The photodisrupted tissue is absorbed into or removed from the cornea through well known means. spots are arranged in successive spiral patterns to photodisrupt and remove a plurality of layers of stromal tissue, with the diameters of the layers being properly sized to result in the desired diopter correction.

The physical characteristics of the laser beam, as well as the manner of focussing the laser beam, are important to the proper performance of the method of the present invention. As indicated above, these considerations are interrelated.

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Pirst, insofar as the characteristics of the laser beam are concerned, several factors are important. The laser beam should have a wavelength that allows the light to pass through the cornea without absorption by the corneal tissue. Accordingly, the light in the laser beam will not be absorbed as the beam transits through the cornea until it reaches the focal spot. Generally, the wavelength should be in the range of 0.3 micrometer (μm) to 3μm, with a wavelength of 1053 nanometers (nm) being preferred. The irradiance of the beam for accomplishment

of photodisruption of stromal tissue at the focal spot should be greater than the threshold for optical breakdown of the tissue. The irradiance which will cause optical breakdown of stromal tissue is approximately 200 GW/cm². The irradiance preferably should not be more than ten times greater than the threshold for optical breakdown and, in any event, not more than one hundred times greater than the threshold. Further, the pulse repetition frequency of the pulsed laser beam is preferably in the range of approximately 1 to 10 kHz.

Second, insofar as the focussing of the laser beam is concerned, spot size, spot configuration, and spot pattern are all important. The spot size of the focused laser beam should be small enough to achieve optical breakdown of stromal tissue at the focal spot. Typically, this requires the spot size to be approximately $10\mu m$ in diameter. Additionally, it is preferable that the spot configuration be as close to spherical as possible. To achieve this configuration for the spot it is necessary that the laser beam be focused from a relatively wide cone angle. For the present invention, the cone angle will preferably be in the range of 15° to 45°. Finally, the spots must be arranged in a pattern that is optimal for creating a cavity of the desired shape. The subsequent deformation of the cavity results in the ultimate reshaping of the cornea in the desired fashion to achieve a desired refractive effect.

To perform intrastromal photodisruption in accordance with the method of the present invention, the laser beam is focused at a first selected spot at a starting point in the stroma. For myopic corrections, the starting point is preferably on the optical axis of the eye at a location behind the epithelium. The laser beam is then activated and stromal tissue at the first spot is photodisrupted. Importantly, because spot size and configuration and the irradiance level of the laser beam are closely controlled for the present invention, the volume of stromal tissue

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which is photodisrupted and removed at the focal spot is carefully controlled. Preferably, this volume is about the same as the volume occupied by the focal spot, or typically about a $10\mu m$ diameter spherical volume.

Next, the laser beam is focused at a second selected 5 spot in the stroma. The second spot lies in a plane containing the first focal spot, with the plane being perpendicular to the optical axis of the eye. It should be noted, however, that during photodisruption of the stromal tissue, a cavitation bubble results which has a diameter 10 which is up to about twice the diameter of the focal spot. Therefore, the second focal spot is selected at a point in which is substantially the stroma adjacent to cavitation bubble resulting from the first focal spot. Again, the laser beam is activated and stromal tissue at 15 the second spot is photodisrupted to add to the volume of stromal tissue which had previously been photodisrupted. Because of the placement of the second spot relative to the cavitation bubble from the first spot, there is some overlap between the cavitation bubbles at the two spots. 20 This process is continued, proceeding from point to point along a planar spiral through the stroma, until a $10\mu\mathrm{m}$ thick layer of stromal tissue has been photodisrupted and removed. The layer of photodisrupted 25 perpendicular to the optical axis.

For effective vision correction of the eye using intrastromal photorefractive keratectomy techniques, it is preferable that tissue photodisruption be accomplished at a plurality of adjacent points in a patterned sequence to create a plurality of layers of tissue removal. The object is to create a dome shaped cavity within the stromal tissue. The dome shaped cavity subsequently collapses, reshaping the corneal surface. The present invention contemplates that the adjacent focal spots in a given layer of the stroma are all located in a plane perpendicular to the optical axis of the eye, and that the pattern of spots

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in each layer is a spiral pattern which is substantially centro-symmetric to the optical axis of the eye. result is a plurality of flat layers of photodisrupted stromal tissue, each layer being perpendicular to the optical axis. In accordance with the present invention, a plurality of superposed photodisrupted layers can be created by first photodisrupting the layer which is to be farthest from the epithelium, followed by successive photodisruption of additional layers in an anterior progression. Each successive layer in the anterior progression has a smaller diameter than the previous layer. The amount by which each layer is smaller than the previous one is determined by a particular geometric model which has been devised to result in the creation of the desired dome shaped cavity. Regardless of the number of layers created, it is important that every layer be at a safe distance from the epithelium, e.g. no closer than approximately 30 μ m.

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BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of this invention, as well as the invention itself, both as to its structure and its operation will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

Figure 1 is a cross sectional view of the cornea of an eye shown in relationship to a schematically depicted laser unit;

Figure 2 is a cross sectional view of the cornea of an eye showing the anatomical layers thereof;

Figure 3 is a schematic representation of the relative positioning of adjacent laser beam spots and the resultant overlapping disruption of stromal tissue which occurs during implementation of the method of the present invention; and

Figure 4 is a plan view schematic representation of a predetermined spiral pattern of focal spots and the resultant layer in which stromal tissue is photodisrupted by implementation of the method of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to Figure 1, a cross section of part of an eye is shown and generally designated 10. For reference purposes, the portion of eye 10 which is shown includes the cornea 12, the sclera 14 and the lens 16. Further, in accordance with standard orthogonal ocular referencing coordinates, the z-axis or z direction is generally oriented on the optical axis of the eye 10. Consequently, the x and y directions establish a plane which is generally perpendicular to the optical axis.

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As best seen in Figure 2, the anatomy of the cornea 12 of an eye 10 includes five different identifiable tissues. The epithelium 18 is the outermost tissue on the exterior of the cornea 12. Behind the epithelium 18, and ordered in a posterior direction along the z-axis, are Bowman's membrane 20, the stroma 22, Descemet's membrane 24, and the endothelium 26. Of these various tissues, the region of most interest to the present invention is the stroma 22.

Returning for the moment to Figure 1, it will be seen that the method of the present invention incorporates a laser unit 28 which must be capable of generating a pulsed laser beam 30 having certain characteristics. Importantly the pulsed laser beam 30 should be monochromatic light having a wavelength (λ) which will pass through all tissues of the cornea 12 without interacting with those tissues. Preferably, wavelength (λ) of laser beam 30 will be in the range of from three tenths of a micron to three microns (λ =0.3 μ m to 3 μ m). Also, the pulse repetition rate of laser beam 30 should be approximately in the range of from one hundred Hertz to one hundred thousand Hertz (0.1-100 kHz).

An additional factor of great importance to the present invention is that the irradiance of laser beam 30 must be circumscribed and well defined. The main concern here is that the irradiance of beam 30 will, in large part, determine the photodisruptive capability of pulsed laser beam 30 on tissue of the stroma 22.

Irradiance, or radiant flux density, is a measure of the radiant power per unit area that flows across a surface. As indicated by the following expression, the irradiance of laser beam 30 is a function of several variables. Specifically:

Irradiance = (pulse energy) (pulse duration)(spot size)

From the above expression for irradiance it can be appreciated that, for a constant level of irradiance, the irradiance is proportional to the amount of energy in each pulse of beam 30. On the other hand, irradiance is inversely proportional to pulse duration and spot size. The significance of this functional relationship stems from the fact that the irradiance of pulsed laser 30 should be approximately equal to the optical breakdown threshold for stromal tissue 22. This threshold is known to be about two hundred gigawatts per square centimeter (200 GW/cm²). Insofar as each factor's contribution to irradiance is concerned, it is important to recognize that no one factor can be considered individually. Instead, the pulse energy, pulse duration and focal spot size of laser beam 30 are interrelated, and each characteristic is variable.

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For purposes of the present invention, the pulse duration of pulses in laser beam 30 is preferably in the range of from one hundred femtoseconds to ten nanoseconds, and preferably in the range of one to one hundred pico seconds (1-100 psec). As for the spot size to which each pulse is focused, the determinative consideration is that the spot size should be small enough to achieve optical

breakdown in a volume of stromal tissue 22 which is approximately equal to the volume of the focal spot. This relationship is perhaps best seen in Figure 3.

In Figure 3, a succession of focal spots 32a-f are shown. All focal spots 32a-f are substantially spherical, or slightly ellipsoidal, and have substantially the same volume. As such, they can each be characterized as having a diameter 34. Focal spots 32a-f are shown arranged in a straight line 50 for the sake of simplicity of the drawing, but as will be explained, for the present invention, it is 10 preferable for the focal spots 32a-f to be arranged on a spiral path. Figure 3 also shows the general relationship between each focal spot 32a-f and the associated cavitation bubble 36a-f which results when laser unit 28 is activated 15 to irradiate a focal spot 32a-f. The cavitation bubble 36a-f, like the associated focal spot 32a-f, will be generally spherical and can be characterized by a diameter 38. As indicated above, it is preferable that diameter 38 of each of cavitation bubbles 36a-f be the same as the diameter 34 of the corresponding focal spot 32a-f. however, cannot always be achieved. In any event, it is important that the volume of cavitation bubble 36a-f not be significantly larger than the volume of the focal spot 32af. For the present invention, it is important that the 25 diameter 34 of focal spots 32a-f be less than about one hundred microns (100 mm), and preferably about 10 mm. preferable that the diameter 38 of cavitation bubbles 36a-f be no more than about twice the diameter 34 of focal spots 32a-f.

As indicated above, the focal spot 32a-f is substantially spherical. To configure focal spot 32a-f as close as possible to a sphere, rather than as an elongated ellipsoid, it is necessary for laser beam 30 to be focused through a rather wide cone angle 40 (see Figure 1). For purposes of the method of the present invention, cone angle 40 should be in the range of from fifteen to forty five

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degrees (15°-45°). Presently, the best results are known to be achieved with a cone angle of about thirty six degrees (36°).

For the practice of the method of the present invention, it is first necessary for the physician to somehow stabilize the eye 10. After the eye 10 has been stabilized, laser beam 30 is focused on a focal spot 32a at a first selected focal point 42a in the stroma 22. Specifically, for many procedures, the first focal point 42a is located generally on the z-axis 44 behind the Bowman's membrane 20. As used here, "behind" means in a posterior direction or inwardly from the Bowman's membrane. Once laser beam 30 is so focused, the laser unit 28 is activated to irradiate the focal spot 32a at first focal point 42a. The result is that a cavitation bubble 36a is formed in stromal tissue 22, and a corresponding volume of stromal tissue is disrupted and removed from the stroma 22.

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The physical consequences of photodisruption of stromal tissue 22 at the first focal point 42a, and at other focal points 42b-f in the stroma 22, are manifold. Some tissue around the focal point 42a-f is, of course, removed. Additionally, however, by-products such as carbon dioxide (CO_2) , carbon monoxide (CO), nitrogen (N_2) and water (H_2O) are formed. As stated above these by-products create a cavitation bubble 36a-f in the tissue of stroma 22. The volume of tissue removed is approximately the same as the volume of the cavitation bubble 36a-f.

As indicated in Figure 3, once the cavitation bubble 36a has been created, the laser beam 30 is repositioned for refocussing at another point 42b. In Figure 3 it is shown that the second focal point 42b is substantially adjacent to first focal point 42a and that both the second focal point 42b and first focal point 42a lie on a path 50. Importantly, the distance along path 50 between first focal point 42a and second focal point 42b is selected so that the adjacent volumes of disrupted tissue in cavitation

bubbles 36a,b will overlap. In effect, the size of the cavitation bubbles 36a-f of disrupted tissue volume will determine the separation distance between selected focal points 42a-f along the path 50. As implied here, subsequent focal points 42c et seq. will also lie on the predetermined path 50 and the disrupted tissue volume at any respective focal point 42 will overlap with the volume of tissue disrupted at the previous focal point in stroma 22. Consequently, the separation distance between focal points 42 on path 50 must be established so that tissue removal along the path 50 will be continuous.

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Figure 4 shows a plan view of a photodisrupted layer 52 as seen looking toward the eye 10 along z-axis 44. Also, Figure 4 shows that the first focal point 42a and the sequence of subsequent points 42b-f all lie along the path 50. Further, Figure 4 shows that the path 50 can be set as a pattern 62 and, as shown in Figure 4, this pattern 62 can be a spiral pattern. It is to be appreciated that the spiral pattern 62 can be extended as far as is desired and necessary to create the layer 52 of disrupted tissue volumes 36. Further, it is to be appreciated that layer 52 may be curved to generally conform to the shape of the cornea's external surface. It is also to be appreciated that the final pattern 62 will be approximately centrosymmetric with respect to the optical axis (z-axis 44) of the eye 10.

Referring back to Figure 2, it will be seen that a plurality of disrupted tissue volumes 36 can be juxtaposed to establish a continuous layer 52 of disrupted stromal tissue. Only a few of the disrupted tissue volumes 36 are shown in layer 52, for the sake of clarity of the drawing, but it should be understood that the entire layer 52 is disrupted as discussed above. As shown in Figure 2, a plurality of layers can be created in stroma 22 by the method of the present invention. Figure 2 shows a layer 54 which is located in front of the layer 52 and a layer 56

which is located in front of the layer 54. Layers 58 and 60 are also shown, with layer 60 being the most anterior and smallest in diameter. As with layer 52, layers 54, 56, 58, and 60 are entirely created by a plurality of disrupted tissue volumes 36. At least ten of these layers can be so created, if desired.

Whenever a plurality of layers are to be created, it is important that the most posterior layer be created first, and that each successive layer be created more anteriorly than any previously created layer. For example, to create layers 52, 54, 56, 58, and 60, it is necessary to start first with the creation of the layer 52. Then, in order, layers 54, 56, 58, and 60 can be created.

There are limitations as to how close any layer can be to the epithelium 18 in order to avoid photodisruption of Bowman's membrane 20 and the epithelium Accordingly, no disrupted tissue volume 36 in any closer to the epithelium 18 should be approximately thirty microns (30 μ m). Therefore, because it is anticipated that each layer will effectively encompass approximately a ten to fifteen micron thickness of tissue, it is necessary that first layer 52 be created at an appropriate location so that neither layer 52 nor any subsequent layer should eventually be located closer to the epithelium 18 than thirty microns.

For a required myopic correction, it is desired to decrease the amount of corneal curvature by a given number of diopters (D), by increasing the corneal radius of curvature. Such a change in corneal curvature is accomplished by removing certain layers of the stromal tissue to create a dome shaped cavity entirely within the stromal layer 22. This cavity will then collapse, resulting in a flattening of the corneal anterior surface. This flattening will achieve the desired corneal curvature change. The desired corneal curvature change D in diopters can be computed according to the following equation:

$$D = \frac{2(n-1)\left(\rho_0 \left[1 - \left(1 - \left(\frac{d_0}{2\rho_0}\right)^2\right]^{1/2}\right] - Nt\right)}{\left(\rho_0 \left[1 - \left(1 - \left(\frac{d_0}{2\rho_0}\right)^2\right]^{1/2}\right] - Nt\right)^2 + \frac{d_0^2}{4}} - \left(\frac{n-1}{\rho_0}\right)$$

where N is the selected number of intrastromal layers to be used to achieve the curvature change. The thickness of each layer, such as $10\mu m$ in the example given, is represented by t. The index of refraction of the cornea is represented by n. The corneal radius of curvature is ρ , with ρ_0 being the preoperative radius. The selected outer diameter of the intrastromal cavity to be created, keeping in mind the minimum required separation from the epithelium 18, is given by d_0 . This selected outer diameter becomes the diameter of the first layer to be created. More effect is produced with smaller outer cavity diameters, and with more layers. The sensitivity to cavity diameter decreases sharply over a cavity diameter of approximately 5 mm.

For myopic correction, the diameter of each layer 52, 54, 56, 58, and 60 is smaller than the diameter of the layer previously created, to create a dome shaped cavity with its base oriented posteriorly, and its crown oriented anteriorly. A geometric analysis of the change in corneal curvature upon collapse of an intrastromal cavity has revealed the optimum shape of the cavity. The appropriate diameter for each layer, d_i , to achieve a desired correction of the anterior corneal curvature, is calculated according to the following equation:

$$d_{i}=2\rho_{0}\left(1-\left[\frac{(\rho_{0}D+n-1)(\rho_{0}-t(i-\frac{1}{2}))^{2}+(\rho_{0}-Nt)[(\rho_{0}D+n-1)(\rho_{0}-Nt)-2(n-1)\rho_{0}]}{2[\rho_{0}^{2}D-Nt(\rho_{0}D+n-1)](\rho_{0}-t(i-\frac{1}{2}))}\right]^{2}\right)^{1/2}$$

where i designates the layer for which the diameter is being calculated, and i = 1, 2, 3, ..., N.

Table 1 lists the layer diameters, in millimeters, which would result from the selection of an outer treatment zone diameter, or cavity diameter, of 6 mm., where N, the number of intrastromal layers, varies from 2 to 10. The first layer has the same diameter as the treatment zone. The preoperative corneal radius of curvature is assumed to be 8 mm., and each layer is assumed to have a thickness of 10 μm. The expected resultant change in corneal radius of curvature is listed at the bottom of each column.

					<u>Tabl</u>	<u>le 1</u>			. ,	
	Layer	N=2	3	4	- 5	6	7	8	9	10
15	1 2 3	6.000 3.044	6.000 4.285 2.490	6.000 4.779 3.721	6.000 5.051 4.286	6.000 5.223 4.622	6.000 5.343 4.847	6.000 5.430 5.009	6.000 5.497 5.130	6.000 5.550 5.225
20	5 6 7 8			2.159	3.334 1.932	3.920 3.047 1.765	4.288 3.635 2.824 1.635	4.543 4.017 3.404 2.644	4.731 4.289 3.792 3.213	4.875 4.495 4.075 3.602
25	9 10	-1.50	02.26	-3.02	-3.78	-4.54	-5.31	1.530 	2.495 1.444 -6.85	3.051 2.368 1.370

While the particular method for performing intrastromal photorefractive keratectomy on the cornea of an eye using a pulsed laser beam as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages herein before stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended to the details of the construction or design herein shown other than as defined in the appended claims.

We claim:

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1. A method for decreasing the curvature of the cornea of an eye, the anatomy of the cornea including an intermediate stroma, which method comprises the steps of:

focusing a pulsed picosecond laser beam to a plurality of selected focal spots in the stroma;

pulsing said laser beam to photodisrupt a plurality of contiguous volumes of stromal tissue at said plurality of focal spots, to create a first flat circular cavity layer within the stroma, said first cavity layer being perpendicular to an optical axis of the eye; and

repeating said focusing step and said pulsing step to create a plurality of additional flat circular cavity layers within the stroma in an anterior progression, said plurality of additional cavity layers having progressively smaller diameters, thereby forming a substantially dome shaped stromal cavity with an anteriorly oriented crown.

A method as recited in claim 1, further comprising the step of calculating said diameter of each
 said cavity layer according to the equation

$$d_{i}=2\rho_{0}\left(1-\left[\frac{(\rho_{0}D+n-1)(\rho_{0}-t(i-\frac{1}{2}))^{2}+(\rho_{0}-Nt)[(\rho_{0}D+n-1)(\rho_{0}-Nt)-2(n-1)\rho_{0}]}{2[\rho_{0}^{2}D-Nt(\rho_{0}D+n-1)](\rho_{0}-t(i-\frac{1}{2}))}\right]^{2}\right)^{1/2}$$

3. A method as recited in claim 1, further comprising the step of selecting said focal spots for each said cavity layer in a spiral pattern.

4. A method as recited in claim 3, further comprising the step of arranging said spiral pattern to be centro-symmetric relative to the optical axis of the eye.

5. A method as recited in claim 1, further comprising the step of selecting a laser beam having a wavelength in a range between three tenths of a micron and three microns, a pulse frequency in a range between one hundred hertz and one hundred thousand hertz, and an irradiance of approximately two hundred gigawatts per square centimeter.

6. A method for decreasing the curvature of the cornea of an eye, the anatomy of the cornea including an intermediate stroma, which method comprises the steps of:

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focusing a pulsed picosecond laser beam to a substantially spherical first selected focal spot in the stroma, said focal spot having a selected diameter;

pulsing said laser beam to photodisrupt a substantially spherical first volume of stromal tissue at said first focal spot;

focusing said laser beam to a substantially spherical second selected focal spot in the stromal layer, said second focal spot being adjacent to said first focal spot, said second focal spot having a diameter substantially the same as said first focal spot;

pulsing said laser beam to photodisrupt a substantially spherical second volume of stromal tissue at said second focal spot;

repeating said focusing step and said pulsing step at a plurality of additional focal spots to photodisrupt additional contiguous volumes of stromal tissue to create a first flat circular cavity layer within the stroma, said first cavity layer having a thickness substantially the same as said selected diameter of said focal spots, said first cavity layer having a selected first diameter, said first cavity layer being perpendicular to an optical axis of the eye; and

repeating said focusing step and said pulsing step to create at least one additional flat circular cavity layer within the stroma, each said additional cavity layer being immediately anterior to a previously formed said cavity layer, each said additional cavity layer having a selected diameter

smaller than said previously formed cavity layer, thereby forming a substantially dome shaped stromal cavity with an anteriorly oriented crown.

7. A method as recited in claim 6, further comprising the step of calculating said diameter of each said cavity layer according to the equation

$$d_{i}=2\rho_{0}\left(1-\left[\frac{(\rho_{0}D+n-1)(\rho_{0}-t(i-1/2))^{2}+(\rho_{0}-Nt)[(\rho_{0}D+n-1)(\rho_{0}-Nt)-2(n-1)\rho_{0}]}{2[\rho_{0}^{2}D-Nt(\rho_{0}D+n-1)](\rho_{0}-t(i-1/2))}\right]^{2}\right)^{1/2}$$

- 8. A method as recited in claim 6, further comprising the step of selecting said focal spots for each said cavity layer in a spiral pattern.
- 9. A method as recited in claim 8, further comprising the step of arranging said spiral pattern to be centro-symmetric relative to the optical axis of the eye.
- 10. A method as recited in claim 6, further comprising the step of selecting a laser beam having a wavelength in a range between three tenths of a micron and three microns, a pulse frequency in a range between one hundred hertz and one hundred thousand hertz, and an irradiance of approximately two hundred gigawatts per square centimeter.

11. A method for creating a cavity in the stroma of an eye to decrease the curvature of the cornea of the eye, the eye having an optical axis, which method comprises the steps of:

calculating a plurality of cavity layer diameters according to the equation

$$d_{i}=2\rho_{0}\left(1-\frac{\left(\rho_{0}D+n-1\right)\left(\rho_{0}-t\left(i-\frac{1}{2}\right)\right)^{2}+\left(\rho_{0}-Nt\right)\left[\left(\rho_{0}D+n-1\right)\left(\rho_{0}-Nt\right)-2\left(n-1\right)\rho_{0}\right]}{2\left[\rho_{0}^{2}D-Nt\left(\rho_{0}D+n-1\right)\right]\left(\rho_{0}-t\left(i-\frac{1}{2}\right)\right)}\right]^{2}\right)^{1/2}$$

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focusing a pulsed picosecond laser beam to a substantially spherical first selected focal spot in the stroma, said focal spot having a selected diameter;

pulsing said laser beam to photodisrupt a substantially spherical first volume of stromal tissue at said first focal spot;

focusing said laser beam to a substantially spherical second selected focal spot in the stromal layer, said second focal spot being adjacent to said first focal spot, said second focal spot having a diameter substantially the same as said first focal spot;

pulsing said laser beam to photodisrupt a substantially spherical second volume of stromal tissue at said second focal spot;

repeating said focusing step and said pulsing step at a plurality of additional focal spots to photodisrupt additional contiguous volumes of stromal tissue to create a first said flat cavity layer within the stroma, said first cavity layer having a first said calculated diameter, said first cavity layer

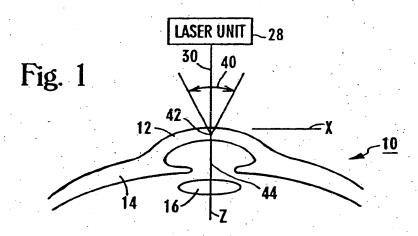
having a thickness substantially the same as said selected diameter of said focal spots, said first cavity layer being perpendicular to an optical axis of the eye; and

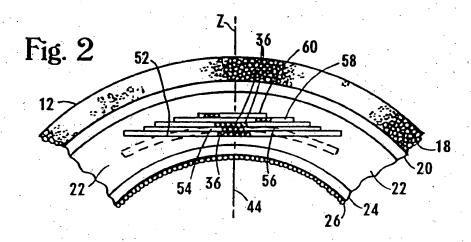
repeating said focusing step and said pulsing step to create a plurality of additional said flat cavity layers within the stroma, each said additional cavity layer being immediately anterior to a previously formed said cavity layer, each said additional cavity layer having a unique said calculated diameter smaller than said previously formed cavity layer, thereby forming a substantially dome shaped stromal cavity with an anteriorly oriented crown.

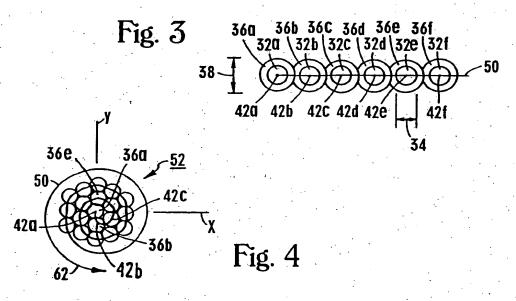
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- 12. A method as recited in claim 11, further comprising the step of selecting said focal spots for each3 said cavity layer in a spiral pattern.
 - 13. A method as recited in claim 12, further comprising the step of arranging said spiral pattern to be centro-symmetric relative to the optical axis of the eye.
- 14. A method as recited in claim 11, further comprising the step of selecting a laser beam having a wavelength in a range between three tenths of a micron and three microns, a pulse frequency in a range between one hundred hertz and one hundred thousand hertz, and an irradiance of approximately two hundred gigawatts per square centimeter.







SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

Interminal application No. PCT/US96/12556

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A. CLASSIFICATION OF SUBJECT MATTER IPC(6): A61N 5/02 US CL: 506/5 According to International Patent Classification (IPC) or to both national classification and IPC								
B. FIELDS SEAR								
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	ion searched (classification system followe	d by classification symbols)						
U.S. : 606/3-6, a	nd 10-18							
Documentation search	ed other than minimum documentation to th	e extent that such documents are included	in the fields searched					
Electronic data base o	onsulted during the international search (na	ime of data base and, where practicable	search terms used)					
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C. DOCUMENTS	CONSIDERED TO BE RELEVANT							
Category* Citati	ion of document, with indication, where ar	propriate, of the relevant passages	Relevant to claim No.					
Y US 4 docum	,907,586 A (BILLE et al) nent.	13 March 1990, entire	1-14					
Y US 4,	903,695 A (WARNER et al) nent.	27 February 1990, entire	1-14					
Y WO S	94/09849 A (SWINGER et nent.	al) 11 May 1994, entire	1-14					
Purther docume	ents are listed in the continuation of Box C	. See patent family annex.						
	es of cited documents:	"T" Inter document published after the inter date and not in conflict with the applica	rnational filing date or priority tion but cited to understand the					
"A" document definition to be of particular	ng the general state of the art which is not considered ar relevance	principle or theory underlying the inv	ntion					
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cited to establish the publication date of another citation or other special renson (as special) Of document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combinated with one or more other such document, such combination								
2000	had prior to the international filing data but hear then	command was one or more other such being obvious to a person skilled in the "&" document member of the same patent	c art					
the priority date claimed								
Date of the setual completion of the international search Of NOVEMBER 1996 Date of mailing of the international search report 19 NOV 1996								
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Authorized officer Diane J. Smith for								
Box PCT Washington, D.C. 20231 DAVID SHAY								
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